Exhibit 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

Lead Plaintiff John C. LEVON, individually and on behalf of all others similarly situated, Plaintiffs, v. CORMEDIX INC., KHOSO BALUCH, ROBERT COOK, MATTHEW DAVID, PHOEBE MOUNTS, JOHN L. ARMSTRONG, and JOSEPH TODISCO, Defendants.	**Civil Action No. 21-14020 (JXN) (CLW)** **OPINION**

NEALS, District Judge:

Before the Court is Defendants CorMedix Inc., Khoso Baluch, Robert Cook, Matthew David, Phoebe Mounts, John L. Armstrong, and Joseph Todisco's (collectively, "Defendants") Motion to Dismiss the Third Amended Consolidated Class Action Complaint ("TAC"), pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4 (ECF No. 104); Plaintiff's opposition (ECF No. 106); and Defendants' Reply (ECF No. 107). Jurisdiction is proper under 28 U.S.C. § 1331. Venue is proper under 28 U.S.C. § 1391(b). The Court has carefully considered the parties' written submissions and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1(b). For the reasons stated below, Defendants' motion to dismiss is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY[1]

Plaintiff John C. Levon brings this putative securities class action on behalf of himself, and all others similarly situated who purchased or otherwise acquired common stock of CorMedix Inc. ("CorMedix" or the "Company") between October 16, 2019, and August 8, 2022 (the "Class Period"), and who were damaged thereby. (TAC ¶¶ 1, 19, ECF No. 97). CorMedix is a biopharmaceutical company headquartered in New Jersey, focused on the development and commercialization of products for the prevention and treatment of infectious diseases. Its lead product candidate, DefenCath (formerly known as Neutrolin), is a catheter lock solution designed to prevent bloodstream infections in patients undergoing hemodialysis. (*Id.* ¶¶ 2, 47).

The action arises out of CorMedix's efforts to obtain U.S. Food and Drug Administration ("FDA") approval of its New Drug Application ("NDA") for DefenCath. Plaintiff alleges that throughout the Class Period, Defendants made materially false and misleading statements and omissions concerning the Company's ability to secure FDA approval. (*Id.* ¶¶ 3–5). Specifically, Plaintiff contends that Defendants misrepresented the regulatory readiness and compliance of CorMedix's third-party manufacturing organization, ROVI Contract Manufacturing, S.L. ("ROVI"), and a key active pharmaceutical ingredient ("API") supplier. (*Id.* ¶¶ 3–5, 80–87). According to Plaintiff, an internal audit conducted in 2018, concluded that ROVI would not pass an FDA inspection due to systemic manufacturing deficiencies, yet Defendants allegedly concealed these findings while repeatedly assuring investors that all manufacturing issues had been resolved. (*Id.* ¶¶ 81–87, 104–08, 112). Plaintiff further alleges that Defendants raised over $60 million in capital during the Class Period through public offerings, while continuing to

[1] The following factual allegations are taken from Plaintiffs' Third Amended Complaint, which are accepted as true. *Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010).

mislead investors about DefenCath's regulatory prospects. (*Id.* ¶¶ 16–17, 89, 102–03, 139–41).

On February 26, 2021, the FDA issued a Complete Response Letter ("CRL") identifying multiple deficiencies at ROVI, including issues involving aseptic process validation, quality assurance, and data integrity, which prevented approval of the NDA. (*Id.* ¶¶ 20, 178–83). CorMedix publicly disclosed the FDA's rejection on March 1, 2021, causing a decline in its stock price. (*Id.* ¶ 21). Defendants subsequently announced that they would work with ROVI to address the FDA's concerns. (*Id.* ¶ 22). CorMedix resubmitted the NDA on February 28, 2022. (*Id.* ¶ 144). However, the FDA issued a second CRL on August 4, 2022, citing unresolved deficiencies at both ROVI and the API supplier, including a failure to ensure cGMP (current Good Manufacturing Practice) compliance. (*Id.* ¶¶ 33, 193–217). The Company disclosed this second CRL on August 8, 2022, prompting another drop in its share price. (*Id.* ¶ 36). Plaintiff alleges that both the first and second CRLs stemmed from the same core issues identified in the 2018 audit, which Defendants never disclosed. (*Id.* ¶¶ 81–87, 178–217).

On July 22, 2021, Plaintiff filed the initial class action complaint. (ECF No. 1). On December 14, 2021, Plaintiff filed the First Amended Complaint, asserting claims under both the Securities Act of 1933 and the Securities Exchange Act of 1934. (ECF No. 43) (the "First Am. Comp."). On March 28, 2022, Defendants moved to dismiss the Consolidated Amended Class Action Complaint.(ECF No. 57).[2] On August 30, 2022, the parties entered a stipulation allowing the filing of a Second Amended Complaint and permitting Defendants to file a motion to dismiss in response thereto. *See* ECF No. 75. On December 9, 2022, the Court granted in part and denied

[2] On February 21, 2022, Defendants moved to dismiss. (ECF No. 50). The Court administratively terminated the motion at ECF No. 50 based on the parties' joint stipulation amending the briefing schedule. *See* ECF No. 55. The motion to dismiss was refiled under ECF No. 57.

in part the motion, dismissing Plaintiff's Securities Act claims with prejudice while allowing Plaintiff to amend the Exchange Act claims. (ECF Nos. 65–66).

On October 10, 2022, Plaintiff filed a Second Amended Complaint ("SAC") alleging claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5. (ECF No. 79). On November 23, 2022, Defendants moved to dismiss the SAC. (ECF No. 86). On March 21, 2024, the Court denied Defendants' motion without prejudice and granted Plaintiff leave to amend. (ECF No. 91).

On April 22, 2024, Plaintiff filed the operative TAC. (ECF No. 97). The TAC again alleges that Defendants violated Section 10(b) and Section 20(a) of the Exchange Act and Rule 10b-5 by issuing materially misleading statements concerning the regulatory status and manufacturing readiness of DefenCath. (TAC ¶¶ 5, 40, 80–87, 104–12, 178–217, 293).

Defendants moved to dismiss the TAC with prejudice on June 6, 2024. (ECF No. 104). On July 22, 2024, Plaintiff opposed. (ECF No. 106). On August 21, 2024, Defendants replied. (ECF No. 107). Defendants' motion to dismiss is now ripe for adjudication.

II. LEGAL STANDARD

A. Rule 12(b)(6)

Rule 8 requires that a pleading include "a short and plain statement of the claim showing that the pleader is entitled to relief" and provide the defendant with "fair notice of what the claim is and the grounds upon which it rests[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation and internal quotations and ellipses omitted). On a Rule 12(b)(6) motion, the "facts alleged must be taken as true" and dismissal is not appropriate where "it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (citation omitted). A complaint will survive a motion

to dismiss if it provides a sufficient factual basis to state a facially plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To determine whether a complaint is sufficient, the Third Circuit requires a three-part inquiry: (1) the court must first recite the elements that must be pled in order to state a claim; (2) the court must then determine which allegations in the complaint are merely conclusory and therefore need not be given an assumption of truth; and (3) the court must "assume the[] veracity" of well-pleaded factual allegations and ascertain whether they plausibly "give rise to an entitlement for relief." *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010) (citations omitted).

Motions to dismiss in a Section 10(b) action under the Securities Exchange Act, similarly, follow a three-step process. First, as with any Rule 12(b)(6) motion, courts must "accept all factual allegations in the complaint as true." *Winer Family Tr. v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007). Second, "courts must consider the complaint in its entirety." *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)). Third, in determining whether the pled facts give rise to a "strong" inference of scienter, the court must take into account plausible opposing inferences. *Id.*; *Cont'l Gen. Ins. Co. v. Olafsson,* No. CV 23-3662 (ZNQ) (JBD), 2024 WL 4263211, at *4–5 (D.N.J. Sept. 23, 2024).

Fraud-based claims brought under the Securities Exchange Act, and alleged as part of a private securities class action, are additionally subject to the heightened pleading requirements of both Rule 9(b) and the Private Securities Litigation Reform Act, 15 U.S.C. § 78u, *et seq.*, (the "PSLRA"). *See In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir. 2006); *see also In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances

constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see Frederico v. Home Depot*, 507 F.3d 188, 200–02 (3d Cir. 2007) (noting that a court may grant a motion to dismiss a fraud-based claim if the plaintiff fails to plead with the required particularity). Particularity requires sufficient details to put the defendant "on notice of the precise misconduct with which [it is] charged." *Id.* at 201 (alteration in original) (quoting *Lum v. Bank of Am.*, 261 F.3d 217, 223–24 (3d Cir. 2004) (abrogated on other grounds)) (internal quotation marks omitted). A plaintiff must plead "the who, what, when, where and how" of the alleged fraud. *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016).

The PSLRA provides two distinct pleading requirements, both of which must be met for a securities complaint to survive a motion to dismiss. *Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009). Both provisions of the PSLRA require facts to be pled with "particularity." *Id.* at 253. A complaint must: (1) "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading"; and (2) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," *i.e.*, scienter. 15 U.S.C. § 78u-4(b)(1)-(2).

B. Rule 9(b) and the PSLRA

The scienter requirement under the PSLRA is satisfied only if the complaint pleads "an inference of scienter [that] is cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc*, 551 U.S. at 314. In the Third Circuit, scienter may be established by alleging either (1) a motive and opportunity to commit fraud or (2) "circumstantial evidence of either reckless or conscious behavior." *Inst'l Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 267 (3d Cir. 2009) (quoting *In re Advanta Corp. Sec. Litig.*, 180 F.3d 524, 534–35 (3d Cir. 1999)). The Third Circuit has repeatedly held that allegations of recklessness—defined as "highly

unreasonable conduct which is an extreme departure from the standards of ordinary care"—may satisfy the scienter requirement for securities fraud. *In re Advanta Corp. Sec. Litig.*, 180 F.3d 524, 535 (3d Cir. 1999).

III. DISCUSSION

Defendants contend that the TAC fails to meet any of the required elements of a securities fraud claim. (Defs.' Br. at 3). Defendants assert Plaintiff fails to plead facts supporting the "compelling" inference of scienter required by the PSLRA. (Defs.' Br. at 3). Plaintiff asserts to the contrary that the TAC contains detailed allegations of contemporaneous knowledge, including confidential witness statements, internal audit reports, and FDA communications known to Defendants at the time of their alleged misstatements. (Pl.'s Br. at 27).

1. Plaintiffs Adequately Allege Material Misrepresentation

To adequately plead material misrepresentation under the PSLRA, plaintiffs must plead with particularity each alleged material misstatement, identifying "the reason or reasons why each flagged statement is false or misleading – or how an omission makes another disclosure false or misleading." *In re Galena Biopharma, Inc. Sec. Litig.*, 336 F. Supp 3d 378, 393 (D.N.J. 2018). Materiality is determined "if there is a substantial likelihood that [a fact or omission] would have been viewed by [a] reasonable investor as having significantly altered the 'total mix' of information available to the investor." *In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *11 (D.N.J. May 19, 2017). Particularity "requires that plaintiffs plead the 'who, what, when, where and how.'" *In re Galena*, 336 F. Supp. 3d at 388. However, "Rule 9(b) and the PSLRA do not insist upon irrefutable evidence of a statement's falsity at the pleading stage; rather, a complaint must contain particularized factual allegations that plausibly allege that a statement was misleading." *City of Warren Police and Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668,

681 (3d Cir. 2023). The statement or omissions must also "have been misleading at the time it was made; liability cannot be imposed on the basis of subsequent events." *Id.* at 693.

Furthermore, "when an allegation of fraud is based upon nondisclosure, there can be no fraud absent a duty to speak." *Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 281 (D.N.J. 2007). "[S]uch a duty to disclose may arise [only] when…[there was] an inaccurate, incomplete or misleading prior disclosure [requiring] a corrective statement." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 281 (D.N.J. 2007). "Disclosure is required under § 10(b) and Rule 10b-5 when 'necessary to make … statements made, in light of the circumstances under which they were made, not misleading.'" *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022). Otherwise put, "there is no affirmative duty to disclose all material information, but such a duty may arise when a company chooses 'to speak about a material subject to investors.'" *Id.*

Defendants categorize the alleged material misrepresentations into four groups: (1) true statements before the first CRL; (2) true statements after the first CRL; (3) forward-looking statements; and (4) opinion/non-actionable statements. (Defs.' Br. at 19, 21, 24, 26).

Plaintiff categorizes Defendants' alleged misstatements and omissions into four groups: (1) those about the then-current state of manufacturing deficiencies; (2) those about being on track; (3) those claiming FDA support; and (4) those about non-manufacturing-related risks. (Pl.'s Br. at 14, 17, 19, 20). Plaintiff also contends that Defendants' misstatements and omissions are not protected opinions or forward-looking statements. (*Id.* at 22).

The Court adopts three of Defendants' categories for the purpose of its analysis.

i. True Statements before the first CRL

First, Defendants state that because "virtually none" of the true statements made before the first CRL amount to "'affirmative characterizations' regarding the likelihood of FDA 'approval'" that the statements do not put "in play" allegedly omitted information. (Defs.' Br. at 19). "Virtually none" is not "none," though. Defendants note a statement Defendants made on March 16, 2020, that "[its CMO] may not be able to comply with the applicable FDA regulatory requirements, which . . . could prevent [Defendants] from ultimately receiving product marketing approval." (Defs.' Br. at 19). By making such a statement, Defendants had a duty to disclose any material information relating to that material subject. *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022) (holding that "there is no affirmative duty to disclose all material information, but such a duty may arise when a company 'chooses to speak about a material subject to investors.'"). Yet, Defendants still allegedly failed to disclose the 2018 Audit, which states that the CMO should not be used because it would not be able to pass an FDA inspection. (TAC ¶ 5). Plaintiff specifically alleges the same in the TAC: that the statement is materially false or misleading because CorMedix omitted material, adverse facts about CorMedix's operations, particularly the deficiencies revealed by the 2018 Audit. (TAC ¶ 193). Additionally, Defendants' argument—that the 2018 Audit does not contradict any of their pre-CRL statements as Defendants do not speak to the CMO's ability to pass FDA inspection—is unpersuasive at this stage of the proceedings. (Defs.' Br. at 21).

Defendants next allege that Plaintiff did not plead any concerns raised by the FDA prior to the First CRL. (Defs.' Br. at 20). Specifically, Defendants claim that the FDA's additional records request did not indicate that the FDA was "concerned" but was instead a part of an ongoing dialogue between Defendants and the FDA. (*Id.* at 20). Defendant, citing *Bauer v. Eagle Pharms.*

Inc., No. 16-3091, 2017 WL 2213147, at *9 (D.N.J. May 19, 2017), contends that such a dialogue cannot give rise to an inference that the FDA expressed concerns. (*Id.* at 20). However, *Bauer* held that "because the Court finds that Plaintiff has not pled falsity as to [certain] statements, there is no basis from which to conclude that the Company's on-going discussions with the FDA, coupled with the core operations doctrine, supports an inference that Defendants knew that the Product's NDA would not be approved." *Id.* at *11. *Bauer* essentially held that because falsity was not adequately pled, dialogue with the FDA cannot support scienter. *Id.*

Here, Plaintiff alleges the falsity of Defendants' statements based on the ongoing dialogue between the FDA and Defendants, specifically Defendants' failure to disclose the FDA's concerns about records submitted during the NDA, which allegedly prompted an additional records request. (TAC ¶¶ 205, 208, 213). Plaintiff alleges that the severity of the FDA's concerns (established through records review and this "ongoing dialogue") was not conveyed to the public, despite Defendant's public statements about the FDA's records review and this "ongoing dialogue." (TAC ¶ 103). Defendants had a duty to disclose the FDA's concerns stemming from its review of records submitted with the NDA when Defendants stated that additional records were requested by the FDA; Defendants commented on a material subject and had a duty to disclose other material information available. *In re Amarin Corp. PLC Sec. Litig.*, No. 21-2071, 2022 WL 2128560, at *3 (3d Cir. June 14, 2022). Relatedly, Plaintiff alleges that Defendants "failed to inform investors that the request for additional information was based on identified deficiencies in the manufacturing process, in addition to mounting deficiencies at the CMO's manufacturing facilities." (TAC ¶ 103). Moreover, Plaintiff pleads with particularity that Defendants misled Plaintiff and the public by failing to disclose that the request for additional information was based on deficiencies at the CMO. (TAC ¶¶ 205, 208, 213).

ii. True Statements after the first CRL

Defendants first argue that they had no duty to disclose material adverse facts about the likelihood of success of the NDA because, "for the most part," Defendants do not comment on this. (Defs.' Br. at 22). Defendants argue that if they had a duty to disclose material adverse facts about the likelihood of success of the NDA, Plaintiff fails to allege the facts that Defendants failed to disclose. (*Id.* at 22). However, Plaintiff does allege that Defendants had a duty but still failed to disclose that its CMO manufactured contaminated vials of Moderna vaccine due to protocols relating to changeover of manufacturing lines at the facility. (TAC ¶ 260). Defendants contend that because the FDA gave no indication that the Moderna contamination would impact its NDA approval, they had no duty to disclose that information. (Defs.' Br. at 22). To support their argument, Defendants cite *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 43 (1st Cir. 2014), which held that its defendant had no obligation to disclose bioreactor failures at one plant where failures "bore no relation to FDA approval of [the NDA]" at *another plant* and where FDA had not given "any indication that the bioreactor failures would hinder approval" of the NDA. (*Id.*). However, *Genzyme* is not instructive here. There is one glaring difference between the present issue and *Genzyme*: the contaminated Moderna vaccines were being manufactured at the same facility that CorMedix contracted to manufacture DefenCath. (TAC ¶ 163). Plaintiff alleges, based on cGMP and Defendants' dialogue with the FDA, that Defendants were responsible for ensuring processes were in place to assure the control of outsourced activities and quality of purchased substances. (TAC ¶ 17). Plaintiff also alleges that:

> [S]ince the CMO manufactured multiple different drug products, Defendants also knew or recklessly ignored that they needed to ensure that its protocols relating to changeover of manufacturing lines . . . met cGMP standards and that deficient protocols relating to changeover of manufacturing lines . . . could and would cause contaminated vials, which would delay the CMO's ability to obtain

> the data requested by the FDA relating to the qualification of the filling operation.

(TAC ¶ 118).

Plaintiff adequately pleads with particularity that Defendants' post-CRL statements are misleading because Plaintiff alleges that Defendants, despite having a duty, failed to disclose material adverse facts regarding the Moderna contamination.

iii. Forward looking statements

A "safe harbor," as afforded under the PSLRA, "immunizes liability from any forward-looking statement[s], provided that: the statement[s] [are] identified as such and accompanied by meaningful cautionary language; or [are] immaterial; or the plaintiff fails to show the statement[s] [were] made with actual knowledge of [their] falsehood." *Institutional Invs. Group v. Avaya, Inc.*, 564 F.3d 242, 254 (3d Cir. 2009). Cautionary statements are "meaningful" when they are "substantive and tailored to the specific future projections, estimates or opinions in the [documents] which the plaintiffs challenge." *OFI Asset Mgmt v. Cooper Tire & Rubber*, 834 F.3d 481, 491 (3d Cir. 2016). Cautionary statements are tailored when they "[identify] important factors that could cause actual results to differ materially from those in the forward-looking statement." *Nat'l Junior Baseball League v. Pharmanet*, 720 F. Supp. 2d 517, 530 (D.N.J. 2010). Boilerplate disclaimers that warn of general risks that accompany investments are not sufficient to immunize a defendant from liability. *OFI Asset Mgmt*, 834 F.3d at 491. Rather, cautionary statements must be "substantive and tailored" and "extensive and specific." *Institutional Invs. Group*, 564 F.3d at 257. Defendants claim that some of the alleged misstatements are forward-looking ("AFL") and accompanied by an adequate cautionary statement, so Defendants are immunized by the PSLRA's safe harbor. (Defs.' Br. at 24). Plaintiff, though, contends that because Defendants failed to disclose adverse events and risks that had already occurred or were occurring,

the AFL are neither truly forward-looking nor supported by truly cautionary language and thus, are not immunized. (Pl.'s Br. at 22-24). Plaintiff alleges in the TAC that the AFL are misleading—not because they fail to "correctly predict that the FDA would not approve DefenCath[,]" but because Defendants concealed events that had occurred or were occurring. (Pl.'s Br. at 22).

This Court is not persuaded by Defendants' argument; the AFL cannot be protected by the PSLRA's safe harbor. Defendants liken their statements to cases that found similar statements regarding FDA to be forward-looking. (Defs.' Br. at 24-25). But central to this issue is not what the AFL state, but rather what the AFL *fail* to caution. Put otherwise, Plaintiff does not allege that the AFL are misleading because their predictions are incorrect but instead alleges that the AFL are misleading because adverse events and risks underlying their predictions were not disclosed. (Pl.'s Br. at 22). Cautionary statements are not truly cautionary when the defendant knows that an identified risk has or will occur. *In re Bristol-Myers Squibb Sec. Litig.*, No. 00-1990, 2005 WL 2007004, *51-52 (D.N.J. Aug. 17, 2005). The Court in *Bristol-Myers* found that "even though statements [were] forward-looking . . . and even if these statements were accompanied by adequate cautionary language, [the] [p]laintiff adequately alleges that [the] [d]efendants had enough information . . . to know that this status would not be attained." *Id.* Essentially, "safe harbor . . . provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon is one foot away." *Id.* For the AFL made before the first CRL, Plaintiff adequately alleges that Defendants failed to disclose concerns that the FDA raised (those which prompted an additional records request as discussed above) and deficiencies at the CMO, which make the AFL misleading. (TAC ¶¶ 205, 208, 213). For the AFL made after the first CRL, Plaintiff adequately alleges in the TAC that Defendants failed to disclose various events and risks that affected the CMO's ability to

address the deficiencies identified in the first CRL that make the AFL misleading. (TAC ¶ 228). Defendants' cautionary statements do not disclose, (and, allegedly, Defendants did not generally disclose) that these events and risks had occurred or were occurring; they state, in one instance, that "[their] CMO *may* not be able to comply with the applicable FDA regulatory requirements, which could result in delays" while allegedly concealing information related to their CMO's ability to comply with the applicable FDA regulatory requirements. (Defs.' Br. at 25).

2. Plaintiffs Adequately Allege Scienter

To plead scienter, the PSLRA requires a plaintiff to allege facts which give rise to a strong inference that the defendant acted with the required state of mind in making misleading statements and/or omissions. 15 U.S.C. §78u-4(b)(2). In the Third Circuit, scienter is sufficiently alleged when the allegations give rise to a strong inference of "either reckless or conscious behavior." *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 524, 534-35 (3d Cir. 1999). Recklessness encompasses "an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 280 (quoting *Advanta*, 180 F.3d at 535). Conscious behavior, meanwhile, exists where a plaintiff "specifically allege[s] defendants' knowledge of facts or access to information contradicting their public statements." *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001).

In analyzing scienter, a court must determine "[w]hen the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *Tellabs*, 551 U.S. at 326. That inference "need not be irrefutable, *i.e.*, of the 'smoking-gun' genre." *Id.* at 326. The analysis must be "case specific" and should "ultimately rest not on the presence or absence of certain types of allegations but on a practical

judgment about whether, accepting the whole factual picture painted by the Complaint, it is at least as likely as not that defendants acted with scienter." *Avaya*, 564 F.3d at 269. The Complaint is clear that Defendants either knew of, or recklessly disregarded, the truth when making their false and misleading statements to investors during the Class Period.

i. Defendants' Public Representations of Expertise and Direct Oversight Support a Strong Interference of Scienter

The Court finds that the Individual Defendants repeated public representations of their regulatory expertise, technical manufacturing experience, and direct oversight over CorMedix's core FDA approval process for DefenCath support a strong inference of scienter. These statements, which Plaintiff alleges falsely reassured investors about compliance and manufacturing readiness, are contradicted by allegations that Defendants had access to internal information detailing ROVI's manufacturing deficiencies and regulatory noncompliance. As such, Plaintiffs have sufficiently alleged that Defendants either knew of or recklessly disregarded material facts undermining their public assurances. To plead scienter under the Private Securities Litigation Reform Act ("PSLRA"), a plaintiff must allege facts giving rise to a "strong inference" that the defendant acted either with intent to deceive, manipulate, or defraud, or at least with recklessness—"an extreme departure from the standards of ordinary care." *In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018). The inference "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc.*, 551 U.S. at 314. Courts in this Circuit have repeatedly found a strong inference of scienter where executives make public statements asserting regulatory expertise or direct oversight, which are later contradicted by internal reports or known deficiencies. *See, e.g., Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 349 (E.D. Pa. 2014) (finding scienter where executives' public statements about FDA compliance were

contradicted by internal findings); *SEB Inv. Mgmt. AB v. Endo Int'l PLC,* 351 F. Supp. 3d 874, 905 (E.D. Pa. 2018) (finding scienter where executives made public statements contradicting information from internal meetings); *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at *8 (D.N.J. June 28, 2024) (holding that public misstatements concerning a flagship product support a strong inference of scienter where the product is critical to the company's core operations and financial viability).

Here, Plaintiffs adequately allege that Defendants Joseph Todisco and John Armstrong made repeated public representations about their direct involvement in the DefenCath regulatory process—particularly regarding manufacturing readiness—while possessing or recklessly disregarding information that contradicted those statements. During the Class Period, Todisco publicly stated that CorMedix was "on track" with the FDA and had "resolved all issues related to manufacturing." (TAC ¶ 6). Similarly, Armstrong told investors in August 2019, that his team had "carried out technical transfer and validation of the manufacturing process," and had submitted multiple NDAs that were ultimately approved. (*Id.*). These were not vague expressions of optimism but detailed assurances asserting personal knowledge and technical mastery. Similarly, CorMedix issued statements in October 2019, that the FDA was "supportive" of the manufacturing program and that the company had "all necessary controls and processes in place for approval." (TAC ¶ 7). The Complaint alleges, however, that Defendants had access to a 2018 audit warning that CorMedix's contract manufacturing organization (ROVI) would likely fail an FDA inspection. (Compl. ¶¶ 5, 40, 79–84). According to former employees, this audit recommended that ROVI not be used. Nonetheless, Defendants continued to reassure investors that manufacturing issues had been resolved. Like the executives in *Frater* and *SEB*, who spoke as authoritative sources while withholding known compliance deficiencies, Todisco and Armstrong's

statements suggest either actual knowledge or at least recklessness in failing to disclose these material issues.

Defendants argue that the 2018 audit should be discounted because it predates the NDA submission by two years and involves a third-party entity. (Defs.' Reply Br. at 2-3). But this ignores that the audit addressed precisely the type of manufacturing deficiencies that later formed the basis of the FDA's Complete Response Letters (CRLs). (TAC ¶¶ 7, 40). And Defendants' argument that ROVI later passed inspection is irrelevant at the pleading stage, where the question is whether the Complaint supports a strong inference of scienter at the time of the alleged misstatements. *See Tellabs, Inc.*, 551 U.S. at 323 (holding that at the pleading stage, courts must consider whether all allegations "collectively" support a strong inference of scienter and must assess the defendant's state of mind "at the time the statements were made," not in hindsight).

Defendants further assert that the absence of insider stock sales undermines scienter. (Defs.' Br. at 11; Defs.' Reply Br. at 3). But courts have repeatedly rejected that contention. *See City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at *13 (D.N.J. June 28, 2024) ("The absence of insider trading is not dispositive."); *In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, No. 15–7658 2017 WL 1658822, at *10 (D.N.J. Apr. 28, 2017). Here, other indicia—such as direct oversight of a single-product company and repeated reassurances to the market—tip the balance toward a culpable inference. *Tellabs, Inc.*, 551 U.S. at 314. Indeed, DefenCath was CorMedix's only product during the Class Period. (TAC ¶ 2; Pls.' Br. at 4). Courts have held that misrepresentations concerning a flagship product are especially probative of scienter. *See City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at *13 (D.N.J. June 28, 2024) ("The importance of the product to the company's financial success supports the inference of scienter."). Because the FDA approval of DefenCath was core to CorMedix's operations, Todisco

and Armstrong—who held themselves out as experts in FDA compliance—are presumed to have known about the company's regulatory and manufacturing failures. *In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 472-73 (E.D. Pa. 2014).

Defendants attempt to characterize their statements as permissible corporate optimism, but these were not vague generalities. They were concrete, repeated assertions about resolved manufacturing issues and regulatory readiness—made by senior executives who portrayed themselves as having firsthand knowledge. (TAC ¶¶ 6–7). Such statements are actionable when contradicted by internal documents, audit findings, and regulatory correspondence. *See Wu v. GSX Techedu Inc.,* No. 20-4457, 2024 WL 3163219 (D.N.J. June 25, 2024); *Dang v. Amarin Corp. PLC*, 750 F. Supp. 3d at 467-469 (D.N.J. 2024).

Accordingly, the Court finds that Plaintiffs have adequately alleged a strong inference of scienter based on Defendants' public representations of their regulatory expertise and direct oversight, which were materially contradicted by internal warnings and adverse regulatory feedback.

ii. Defendants' Access to Contradictory Information Supports a Strong Interference of Scienter

The Court finds that Plaintiffs have adequately pled scienter by alleging that CorMedix executives had access to internal audit findings and other contradictory information concerning serious manufacturing deficiencies that were not disclosed to investors. Under the PSLRA, plaintiffs must allege facts that give rise to a "strong inference" of scienter, meaning a mental state embracing intent to deceive or at least severe recklessness. See *Tellabs, Inc.*, 551 U.S. at 314; 15 U.S.C. § 78u–4(b)(2). In the Third Circuit, a strong inference may arise where a plaintiff pleads that executives had access to internal documents that directly contradicted their public statements. See *Institutional Inv'rs Grp. v. Avaya Inc.*, 564 F.3d 242, 259–60 (3d Cir. 2009).

In *Avaya*, the Third Circuit held that internal reports containing negative data can support scienter when executives make contrary public statements, particularly where confidential witnesses corroborate the executives' access to such information. Courts applying *Avaya* have consistently found scienter adequately alleged when internal audits or internal data—known to executives—contradict positive public messaging. *See, e.g.*, *SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 904–06 (E.D. Pa. 2018); *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001); *Wu v. GSX Techedu Inc.,* No. 20-4457, 2024 WL 3163219 (D.N.J. June 25, 2024). In *Wu*, the court credited specific and corroborated confidential witness accounts that executives had access to internal reports contradicting the company's public financial disclosures. Similarly, in *Stichting Pensioenfonds Metaal en Techniek v. Verizon Commc'ns Inc.*, No. 23-05218, 2021 WL 3540968, at *15–17 (S.D.N.Y. Aug. 10, 2021), access to internal emails and memos warning about inaccuracies supported a finding of scienter.

Here, Plaintiffs allege that Defendants Todisco and Armstrong had access to a 2018 internal audit that warned CorMedix's contract manufacturer, ROVI, was likely to fail FDA inspection due to systemic deficiencies (TAC ¶¶ 79–84). According to two confidential witnesses (FE1 and FE2), this audit was known to senior executives, including Armstrong, and its findings were not disclosed to the public. (*See* Pl.'s Br. at 4–5). Yet throughout the Class Period, Defendants repeatedly reassured investors that manufacturing issues had been "resolved" and the NDA was "on track." (*See* Pl.'s Br. at 6–8). This internal audit directly contradicted Defendants' public statements and fits squarely within the scienter framework articulated in *Avaya* and its progeny. In *SEB*, for instance, scienter was found where executives attended meetings discussing negative trial data while publicly issuing optimistic statements.[3] Likewise, in *Campbell Soup*,[4] weekly

[3] 351 F. Supp. 3d 874.
[4] 145 F. Supp. 2d 574, 599.

internal reports showing poor sales contrasted sharply with public optimism, which the court found indicative of recklessness. Here, Plaintiffs allege no meaningful corrective action was taken in response to the 2018 audit, and the same deficient manufacturer was used when the NDA was resubmitted in 2022—only to be rejected again for the same unresolved issues. (TAC ¶¶ 2, 5, 40, 84). Defendants' argument that the audit was outdated lacks merit. (*See* Defs.' Reply Br. at 2–3). As in *Dang v. Amarin Corp. PLC*, courts recognize that contemporaneous internal documents—such as Form 483s, audits, or CRLs—contradicting public assurances provide "classic evidence of scienter." *Dang v. Amarin Corp. PLC*, 750 F. Supp. 3d 431, 464–65 (D.N.J. 2024).

The fact that CorMedix re-used the same non-compliant CMO without disclosing the audit's findings reinforces the inference of deliberate concealment or recklessness. Further, the reliability of the confidential witness statements is supported by their specificity, consistency, and corroboration with the audit and CRL history (*See* Pl.'s Br. at 31-33). FE1 allegedly authored the 2018 audit report, and FE2 described its dissemination to Armstrong and other senior staff. These details, like those credited in *Wu*, strengthen the inference that CorMedix executives knew of ROVI's deficiencies and concealed this knowledge while assuring investors of compliance. Finally, CorMedix's business during the Class Period centered exclusively on DefenCath, heightening the inference that Defendants were closely involved in and knowledgeable about the FDA approval process. As the court explained in *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at *13 (D.N.J. June 28, 2024), statements regarding a company's core product made with access to contradicting internal data warrant a strong inference of scienter, even absent a motive such as insider stock sales.

Plaintiffs have adequately alleged that Defendants had access to internal documents and data that contradicted their public statements and failed to correct them, supporting a strong

inference of at least severe recklessness under *Tellabs, Inc.*. Thus, the Court finds Plaintiff adequately pleads scienter in terms of the Defendant's access to contradictory information.

iii. The Core Operations Theory Supports an Inference of Scienter

The Court further finds that Plaintiffs have sufficiently pleaded a strong inference of scienter under the core operations doctrine because DefenCath was central to CorMedix's business, and the Individual Defendants had direct oversight of the product's regulatory progress. These facts support the inference that the Defendants were aware of, or recklessly disregarded, the serious manufacturing deficiencies that undermined their public assurances. Under the core operations doctrine, courts may infer scienter when a company's high-ranking executives make materially false or misleading statements about issues central to the company's core business. While the Third Circuit has not adopted a standalone core operations presumption, it has recognized that allegations involving a product or issue that is "critical to a company's core operations" may contribute to a strong inference of scienter when coupled with individualized allegations of knowledge or access to contradictory facts. See *Institutional Inv'rs Grp. v. Avaya Inc.*, 564 F.3d 242, 270 (3d Cir. 2009); *Carmignac Gestion, S.A. v. Perrigo Co.*, No. 17-10467, 2019 WL 3451523, at *16 (D.N.J. July 31, 2019); *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at *13 (D.N.J. June 28, 2024).

In *Avaya*, the Third Circuit acknowledged that a plaintiff may strengthen an inference of scienter by alleging that executives had access to or oversight over internal facts contradicting their public statements, particularly where the subject matter involves core operations. Similarly, *Carmignac* held that when senior executives made statements concerning a product line that accounted for 22% of revenue—and were specifically alleged to have reviewed reports showing declining market share—the scienter requirement was met. *Carmignac Gestion, S.A. v. Perrigo*

Co., No. 17-10467, 2019 WL 3451523, at *16 (D.N.J. July 31, 2019); *see also Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, at *21 (D.N.J. Dec. 27, 2019) (the court also found scienter adequately pled where defendants made public misstatements about a "flagship product" despite internal knowledge of adverse information.).

CorMedix's case is analogous. DefenCath was the company's only commercial product, and its approval was critical to CorMedix's viability. (*See* TAC ¶¶ 5, 40, 293). The Individual Defendants—including Armstrong, the EVP of Technical Operations, and Baluch, the CEO—held themselves out as possessing direct oversight of DefenCath's NDA process and manufacturing readiness. (TAC ¶ 52). As in *Catalent*, scienter can be inferred not just from the product's centrality, but also from the Defendants' public representations of their personal knowledge. *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-737, 2024 WL 3219616, at *13 (D.N.J. June 28, 2024). Courts have rejected scienter arguments where executives were removed from the subject matter, or the product was peripheral to operations. *See, e.g., Hoey v. Insmed Inc.*, No. 16-4323, 2018 WL 902266, at *23 (D.N.J. Feb. 15, 2018). But those facts are not present here. Plaintiffs have alleged that Armstrong and Baluch were not only deeply involved in the NDA process but also received internal audit findings and FDA feedback identifying manufacturing deficiencies that contradicted their public statements. (*See* TAC ¶¶ 5, 40, 85–87, 104, 112). These allegations go beyond mere titles or positions; they demonstrate contemporaneous awareness and direct involvement—key factors that distinguish this case from those where core operations allegations were deemed insufficient.

In *Dang v. Amarin Corp. PLC*, the court applied the core operations doctrine where executives made misleading statements about Vascepa, the company's only product, while ignoring FDA Form 483s and audits identifying significant regulatory risks. *Dang v. Amarin Corp.*

PLC, 750 F. Supp. 3d at 471-472 (D.N.J. 2024). Here, Plaintiffs similarly allege that CorMedix executives knew of a 2018 audit warning that ROVI was unlikely to pass FDA inspection but proceeded to submit the NDA without switching CMOs or disclosing the risk. As in *Dang*, the executives' active roles and knowledge of serious compliance deficiencies support scienter under both the core operations doctrine and the general PSLRA standard. Defendants argue that because ROVI was a third-party CMO, CorMedix cannot be held responsible for its compliance issues. (*See* Defs.' Reply at 2–3). But the FDA regulations clearly place the burden of ensuring CMO compliance on the NDA sponsor. *See* 21 C.F.R. §§ 211.1, 314.50(d)(1)(i). As such, CorMedix could not disclaim responsibility for ROVI's deficiencies. The Individual Defendants repeated public assurances that manufacturing issues had been resolved, in light of contrary internal findings, were misleading and material.

Finally, CorMedix's post-Class Period statements reinforce the inference of scienter. In its March 2023 announcement, the company admitted it did not have "the right team" to address manufacturing deficiencies—an implicit acknowledgment that Armstrong and Baluch had failed in their oversight roles. (*See* Pl.'s Br. at 6). This admission underscores their centrality to the NDA process and supports the conclusion that they were aware of the underlying issues at the time their public statements were made. Because DefenCath was central to CorMedix's operations and the Individual Defendants repeatedly emphasized their expertise and personal oversight, the Court finds that Plaintiffs have adequately pled scienter under the core operations doctrine.

iv. SOX Certifications and Resubmission Efforts Further Support Scienter

The Court finds that Plaintiffs have sufficiently pled a strong inference of scienter based on Defendants' Sarbanes-Oxley ("SOX") certifications and their decision to resubmit the NDA despite their alleged awareness of persistent regulatory deficiencies. These actions support the

inference that Defendants either knew or recklessly disregarded that their public statements were misleading, which is sufficient to survive a motion to dismiss under the PSLRA. To plead scienter under the PSLRA, a plaintiff must allege facts giving rise to a "strong inference" that the defendant acted with the intent to deceive, manipulate, or defraud investors. This inference must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc.*, 551 U.S. at 324. Courts have repeatedly held that SOX certifications can support a strong inference of scienter when executives certify internal controls while aware of or recklessly disregarding serious deficiencies, especially when the issues pertain to core operations. See *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 348–49 (D.N.J. 2007); *In re Toronto-Dominion Bank Sec. Litig.*, No. 17-1665, 2018 WL 6381882, at *19 (D.N.J. Dec. 6, 2018); *In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *22 (D.N.J. Dec. 19, 2019).

In *Intelligroup*, the court found that certifying executives made actionable misstatements by signing SOX certifications despite knowledge of serious internal control failures. The certifications became "false statements in their own right" where executives were aware of red flags or contradictory information. (*Id.* at 348). Similarly, in *Toronto-Dominion Bank*, the court concluded that a strong inference of scienter existed where certifiers failed to disclose known deficiencies despite signing SOX certifications that affirmed the accuracy of financial statements. *In re Toronto-Dominion Bank Sec. Litig.*, No. 17-1665, 2018 WL 6381882, at *19 (D.N.J. Dec. 6, 2018). And in *Celgene*, the court denied a motion to dismiss where defendants certified regulatory compliance despite undisclosed adverse FDA communications related to drug approvals—circumstances comparable to those in this case. *In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *22 (D.N.J. Dec. 19, 2019).

Here, the scienter allegations are at least as compelling. Defendants Armstrong and Baluch signed SOX certifications throughout the Class Period attesting to the adequacy of CorMedix's internal controls, even as they allegedly knew of systemic manufacturing deficiencies at ROVI—CorMedix's contract manufacturing organization—dating back to a 2018 audit. These deficiencies were never remediated and led to repeated Form 483s and Complete Response Letters (CRLs) from the FDA. Nevertheless, Defendants resubmitted the NDA without addressing the core deficiencies. This sequence of conduct—certifying internal controls, failing to disclose known regulatory failures, and proceeding with a flawed NDA—parallels the misconduct that courts in *Intelligroup* and *Celgene* found sufficient to support scienter.

Moreover, Plaintiffs allege that these SOX certifications were not mere formalities. Defendants repeatedly reassured investors that manufacturing issues were resolved, even as internal reports and confidential witness accounts showed otherwise. (*See* TAC ¶¶ 5, 40, 85–87, 104, 112). CorMedix later acknowledged the failure by admitting it lacked the "right team" to handle regulatory challenges when Armstrong and Baluch resigned following the NDA rejection. (TAC ¶ 103). These facts further tie Defendants' SOX certifications to alleged actual knowledge of material risks. Defendants' reliance on *In re Cognizant Tech. Sols. Corp. Sec. Litig.*, No. 16-5805, 2018 WL 3772675 (D.N.J. Aug. 9, 2018), is misplaced. In *Cognizant*, the court declined to infer scienter because plaintiffs failed to allege concrete knowledge of red flags or internal reports undermining the SOX certifications. (*Id.* at 22). In contrast, Plaintiffs here allege specific documents, meetings, and confidential witness testimony showing that Armstrong and Baluch were aware of the unresolved regulatory issues at ROVI when they made public assurances and signed certifications.

The inference of scienter is further strengthened by the strategic timing of the NDA resubmission. Defendants chose to proceed with the same CMO, knowing that FDA observations and the 2018 audit had flagged ongoing violations. As the *Celgene* court explained, misleading the market while withholding adverse regulatory information—particularly when the withheld issues concern a flagship product—is classic evidence of scienter. *In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *22 (D.N.J. Dec. 19, 2019). Because Defendants knowingly or recklessly certified internal controls and proceeded with a deficient NDA despite adverse findings from regulators and internal audits, the Court finds that Plaintiffs have adequately pled a strong inference of scienter in terms of SOX Certification and Resubmission efforts.

v. The Lack of Any Plausible Nonculpable Explanation Reinforces the Inference of Scienter

The Court concludes that Plaintiffs have adequately pled a strong inference of scienter because Defendants have failed to offer any plausible nonculpable explanation for their conduct. When viewed in conjunction with the repeated regulatory failures, concealment of adverse manufacturing findings, and pattern of misstatements, the inference of scienter is at least as compelling as any competing nonfraudulent inference and satisfies the heightened pleading standard under the PSLRA. Under the PSLRA, plaintiffs must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2). Scienter is defined as "a mental state embracing intent to deceive, manipulate, or defraud," or at a minimum, "recklessness." *Tellabs, Inc.*, 551 U.S. at 319–20. Courts must consider all allegations holistically and determine whether "a reasonable person would deem the inference of scienter at least as strong as any opposing inference." *Id.* at 324; *Institutional Inv. Grp. v. Avaya, Inc.*, 564 F.3d 242, 267–68 (3d Cir. 2009).

A recognized factor in favor of scienter is the absence of a plausible, nonculpable explanation. Courts in this District have emphasized that when plaintiffs offer a coherent and factually supported theory of fraud, and defendants fail to identify any comparably plausible innocent explanation, the inference of scienter is strengthened. *See Roofer's Pension Fund v. Papa*, No. 16-2805, 2018 WL 3601229, at *11 (D.N.J. July 27, 2018) ("The lack of any competing inference that is more plausible than Plaintiffs' suggested inference… reinforces a strong inference of scienter."); *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 349 (E.D. Pa. 2014) (rejecting alternative inferences where plaintiffs plausibly alleged intentional or reckless deception).

Here, Plaintiffs have pled a plausible and well-supported theory of scienter: Defendants were aware as early as 2018—based on an internal audit—that ROVI, CorMedix's contract manufacturing organization (ROVI), faced serious compliance issues that could preclude FDA approval. (*See* TAC ¶¶ 20, 88, 178–217). Despite this knowledge and despite receiving a Complete Response Letter (CRL) in 2021, confirming ROVI's deficiencies, Defendants reassured investors that manufacturing issues had been resolved and resubmitted the NDA in 2022, which again failed for similar reasons. (*Id.*) Defendants never disclosed the earlier audit or any of the regulatory red flags to investors.

Defendants' reply fails to provide any equally compelling nonculpable explanation. Instead, they offer post hoc assertions that the problems stemmed from a third-party vendor (ROVI) and that the NDA was eventually approved. (*See* Defs.' Reply Mem. at 2–3). But courts routinely reject "fraud by hindsight" defenses where plaintiffs allege contemporaneous knowledge of red flags. *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-737, 2024 WL 3219616, at *15

(D.N.J. June 28, 2024); *In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, No. 15-7658, 2017 WL 1658822, at *15 (D.N.J.Apr.28,2017).

Moreover, the lack of insider trading or direct financial gain does not negate scienter. The Third Circuit has made clear that "the absence of a motive allegation is not fatal" when the overall factual context supports fraudulent intent. *Avaya*, 564 F.3d at 277. Here, CorMedix had a strong motive to maintain investor confidence and inflated stock prices to facilitate two public offerings totaling $60 million during the Class Period. (*See* TAC ¶¶ 17, 89, 139–41). Defendants' suggestion that they misunderstood the audit's implications or were unaware of ROVI's readiness is less compelling than Plaintiffs' detailed allegations. Courts do not credit vague or unsupported alternative explanations. *Tellabs, Inc.*, 551 U.S. at 323–24. Given the absence of any viable nonculpable inference and the strength of Plaintiffs' factually supported theory, the Court finds that the inference of scienter is both cogent and compelling. Dismissal under Rule 12(b)(6) is therefore unwarranted.

3. Plaintiff adequately alleges loss causation.

To adequately allege loss causation, a plaintiff must plead a causal link between the disclosure of the alleged fraud and the economic harm that was ultimately suffered by the plaintiff. *In re Bradley Pharmaceuticals, Inc. Sec. Litig.*, 421 F. Supp 2d 822, 828 (D.N.J. 2006). The plaintiff must plead that the defendant's "misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security," which relates to the plaintiff's economic loss. *De Vito v. Liquid Holdings Group, Inc.*, No. 15-6969, 2018 WL 6891832, at *39 (D.N.J. December 31, 2018). The PSLRA's and Rule 9(b)'s heightened pleading requirements, as applied in earlier sections of this opinion, are not applicable to loss causation analysis; a plaintiff must only satisfy Rule 8(a)(2)'s pleading standard to adequately plead loss

causation. *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 346 (2005). Rule 8(a)(2) simply requires "a short and plain statement of the claim showing that the pleader is entitled to relief." *Id.* Loss causation, therefore, is adequately pled when a plaintiff alleges that a defendant's misrepresentations "directly or proximately caused, or were a substantial contributing cause of, the damages sustained by [the] plaintiff." *EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 883 (3d Cir. 2000).

The *Dura* Court noted that pleading requirements are not meant to impose a great burden on a plaintiff, and function to provide defendants "with some indication of the loss and the causal connection that [plaintiffs have] in mind." 544 U.S. at 347. *Bradley* applied *Dura* at the motion to dismiss stage of its litigation when holding that its plaintiffs pled sufficient facts to satisfy the loss causation requirement by alleging that the price of Defendant-Company's stocks dropped after the truth regarding Defendants' alleged misrepresentation became known. 421 F. Supp 2d at 828.

Plaintiff relies on two theories to plead loss causation: corrective disclosure and materialization of concealed risk. (Pl.'s Br. at 38). A "plaintiff may adequately plead loss causation by alleging either a corrective disclosure of a previously undisclosed truth that causes a decline in the stock price or the materialization of a concealed risk that causes a stock price decline." *In re Wilmington Tr. Sec. Litig.*, 29 F. Supp. 3d 432, 450 (D. Del. 2014). There is dispute within the District as to whether the Third Circuit has endorsed the materialization of risk theory. *Compare Pharmanet*, 720 F. Supp. 2d at 563 (declining to consider the materialization of risk theory because the Third Circuit has not endorsed it as a way to establish loss causation) and *Glover v. DeLuca*, No. 2:03-0288, 2006 WL 2850448, at *33 (W.D. Pa. Sep. 29, 2006) (acknowledging that the Third Circuit has not explicitly endorsed materialization of risk theory while still considering (but ultimately rejecting) the merits of Plaintiff's materialization of risk

argument) with *McCabe v. Ernset & Young, LLP*, 494 F.3d 418, 429 (3d Cir. 2007) (finding materialization of risk is "consistent" with the Third Circuit's loss causation jurisprudence). However, as the *De Vito* Court recognized, "the ultimate loss causation inquiry under either the corrective disclosure theory or the materialization of a concealed risk theory is the same: whether a 'misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security.'" No. 15-6969, 2018 WL 6891832, at *39 (D.N.J. December 31, 2018). This Court will proceed by evaluating the ACDs by addressing "the ultimate loss causation inquiry" as it relates to this matter. *Id.*

Plaintiff contends that he adequately pled loss causation by alleging: (1) that on five occasions throughout the class period ACDs were disclosed to the market; (2) the information that was provided in each disclosure; and (3) the ways in which each disclosure relates to the concealment, and 4) that stock prices dropped following each disclosure. (Pl.'s Br. at 39).

The first ACD was issued via press release on March 1, 2021, in which CorMedix disclosed that it received its first CRL based on the FDA's review of records requested from the CMO. (TAC ¶ 219). Plaintiff alleges that the first ACD relates to CorMedix's misrepresentations and omissions regarding the "true scope" of the CMO's deficiencies. (TAC ¶ 221). CorMedix stock price fell 54.4%, purportedly as a result of the first ACD. (TAC ¶ 220). The second ACD was issued via press release on April 14, 2021, and stated that, to address the FDA's concerns about the CMO, CorMedix may need to make adjustments and generate more data. Plaintiff alleges that the second ACD relates to CorMedix's misrepresentations and omission regarding the "true scope" of the CMO's deficiencies. (TAC ¶ 237). CorMedix stock price fell 18.36%, purportedly as a result of the second ACD. (*Id.*).

The third ACD was issued via press release and the1Q21 call on May 13, 2021, disclosing that more must be done to address the deficiencies identified by the FDA, specifically process qualification. (TAC ¶¶ 242, 244, 246). Plaintiff alleges that the third ACD relates to CorMedix's misstatements and omissions regarding the "true scope" of the CMO's deficiencies and the amount of time to correct the deficiencies. (TAC ¶ 248). CorMedix stock price fell by 19.97%, purportedly as a result of third ACD. (TAC ¶ 247). The fourth ACD was issued via press release on September 7, 2021, stating that because of delays at the CMO (unrelated to DefenCath) that the timeline to address FDA concerns is uncertain. (TAC ¶ 261). Plaintiff alleges that the fourth ACD relates to CorMedix's misrepresentation of the CMO's ability to pass an FDA on-site inspection, and the concealment of ongoing manufacturing issues at the CMO, potential supply chain risks, and serious, materialized risks about manufacturing deficiencies at their heparin supplier facility. (TAC ¶ 265). CorMedix stock price fell by 27.40%, purportedly as a result of the fourth ACD. (TAC ¶¶ 262-63). The fifth ACD was issued via press release on August 8, 2022, stating that CorMedix received another CRL based on manufacturing issues at its CMO and that DefenCath will not be approved until CorMedix satisfactorily resolves the deficiencies with its CMO. (TAC ¶¶ 281-285). Plaintiff alleges that fifth ACD represents "the truth fully emerging." (TAC ¶ 281). CorMedix stock price fell by 57.45%, purportedly as a result of the fifth ACD. (TAC ¶¶ 281-285).

Defendants argue that the five ACDs are not "truly corrective of any prior statement." (Defs' Br. at 28). Rather, Defendants contend that the disclosures reveal new information about the FDA approval process. (*Id.* at 29). Defendants also argue that Plaintiff never pled that the market discovered a fraud. (Defs' Br. at 28).

The ACDs are allegedly corrective of Defendants' prior statements and omissions. (TAC ¶¶ 219, 236, 242-46, 261, 281). *Bradley* notes that *Dura* only "suggest[s] that the plaintiffs [need]

to have alleged in some fashion that 'the truth became known' before 'the share price fell'" and that *Dura* does not specify what type of events or disclosures or even how specific any disclosures or events must be. 421 F. Supp 2d at 828.

Taking Plaintiff's allegations as true, it does appear that Plaintiff alleged that the market discovered fraud through the ACDs and that it responded accordingly. Defendants are correct in their analysis of *Dura*; it does hold that, even when applying the softer Rule 8(a)(2) pleading requirements, a plaintiff must allege more than purchase price inflation or a stock price drop following the release of any information. 544 U.S. at 346. The *Dura* Court held that loss causation was not adequately alleged because of "the complaint's failure to claim that [the defendant's] share price fell significantly after the truth became known" and consequently the plaintiff's suggestion "that…the allegation of purchase price inflation alone [was] sufficient." *Id.* at 347. However, the Court disagrees with Defendants' application of *Dura* to this matter. Plaintiff does allege multiple times throughout his complaint that Defendants' artificially inflated stock price promptly and drastically fell after each ACD; he submits that each ACD represents the market discovering the truth (or partial truth) of the fraud. (TAC ¶¶ 286-290) ("The price of CorMedix securities declined significantly when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were disseminated and publicly revealed"). Each ACD informed the market that Defendants did or must have previously misstated or omitted – or both – material facts that artificially inflated the stock price.

Plaintiff's allegations are sufficiently pled to meet the Rule 8(a)(2) standard, as were the plaintiff's allegations in *Bradley*. There, the plaintiffs alleged that "the false and misleading statements in the Third Quarter Press Release and . . . 10-Q inflated [defendants'] stock price by $3.50 per share, and that [plaintiffs] suffered actual economic loss . . . when [a] sham transaction,

which was concealed by defendants' misrepresentations and omissions was disclosed to the market causing inflation to be removed from [defendants'] stock price." *Bradley*, 421 F. Supp 2d at 828.

Here, Plaintiff alleges that false and misleading statements and omissions inflated CorMedix's stock price and that Plaintiff suffered actual economic loss when five press releases disclosed to the public the truth of CorMedix's issues with its CMO for DefenCath, causing inflation to be removed from CorMedix's stock price. (TAC ¶¶ 219, 236, 242-46, 261, 281).

IV. CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss (ECF No. 144) is **DENIED**. An appropriate Order accompanies this Opinion.

DATED: June 30, 2025

JULIEN XAVIER NEALS
United States District Judge